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## STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The National Association of Chain Drug Stores ("NACDS") is a non-profit association of nearly 200 retail pharmacy chains. NACDS members operate more than 36,000 retail community pharmacies and dispense approximately 70% of Americans' prescription drugs. Anticompetitive practices by drug manufacturers, such as the practices at issue in this case, harm NACDS members and their customers by maintaining artificially high prices for prescription drugs. NACDS believes that its industry-wide perspective on this important issue will be of assistance to the Court and therefore submits this *amicus curiae* brief in support of the petition for writ of certiorari to the United States Court of Appeals for the Eleventh Circuit.

The Court of Appeals panel held that the patentee lawfully paid challengers to withdraw their challenges to the patent and to stay out of the market. Pet. App. 34a-35a. If left standing, that decision would undermine a careful statutory scheme in which Congress sought to rid the pharmaceutical marketplace of weak or narrow patents that block generic entry. Given the enormous consequences for consumers – consumers whose elected representatives reached a starkly different balance between the interests of patent holders and consumers – review by this Court is appropriate.

## BACKGROUND

### Background of the FTC's Decision

As the 1990s came to a close, consumers stood to benefit from a significant increase in competition between branded and generic pharmaceuticals. More than 40 brand drugs with over $16 billion in annual sales were scheduled to lose patent protection by 2002. Elyse Tanouye & Robert Langreth, *Time's Up: With Patents Expiring on Big Prescriptions, Drug Industry Quakes*, WALL ST. J., Aug. 12, 1997, at A1. And the outlook for

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1. No counsel for a party authored any portion of this brief. No person or entity, other than the named *amicus* and its counsel, made any monetary contribution to the preparation and submission of this brief.

branded drugs beyond 2002 was even dimmer. *See* Theresa Agovino, *Drug Patents Gets Attention of Regulators*, PITT. POST-GAZETTE, Jan. 24, 2002, at E4 (estimating that between 2000 and 2005 one-third of the prescription medicines in the United States, worth more than $30 billion in sales, would lose patent protection). At the same time, there was a dearth of new branded product development. *See, e.g.*, Peter Young, *Troubling Times for Pharma*, 164 CHEMICAL WK. S20 (Sept. 18, 2002) (noting "the widespread problem of weak drug development pipeline profiles among the large branded pharmaceutical companies").

The brand manufacturers responded by employing various "evergreening techniques," *i.e.*, tactics designed to extend exclusivity beyond the patent term or to otherwise impede generic entry. These techniques included improperly listing patents in the Orange Book in order to take advantage of the Hatch-Waxman Act's automatic 30-month stay on generic market entry;[2] switching the product formulation (*e.g.*, from a tablet to a capsule) before a generic enters the market;[3] and restricting ingredient access.[4]

Another such technique was to simply pay the generic challenger to stay out of the market – the "exclusion payment" technique at issue in this case. Some brand manufacturers made such payments to generic manufacturers that were

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2. *See, e.g., In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (improper listing); *Mylan Pharms., Inc. v. Thompson*, 139 F. Supp. 2d 1, 23-24 (D.D.C.), *rev'd*, 268 F.3d 1323 (Fed. Cir. 2001) (improper listing); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 934-36 (N.D. Ill. 1995) (late listing); *FTC v. GlaxoSmithKline*, 202 F.R.D. 8 (D.D.C. 2001) (improper listing).

3. *See FTC Investigates Replacement of Branded Rx With Similar Versions*, FDA Week, Sept. 2, 2005, at § 35 (detailing the FTC investigation into "the practice among brand name drug companies of withdrawing their products shortly before generic competition and introducing slightly different versions").

4. *See, e.g., Eli Lilly & Co. v. American Cyanamid Co.*, No. IP 95-536-C, 2001 U.S. Dist. LEXIS 212, at *4 (S.D. Ind. Jan. 8, 2001) (manufacturer allegedly prevented generic competition by tying up manufacturing capacity).

challenging the validity (or non-infringement) of the brand patent – challenges that Congress expressly encouraged in the Hatch-Waxman Act by granting a bounty for successful challenges. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (granting 180 days of generic market exclusivity to the first ANDA IV filer); *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627, 629 (D.C. Cir. 2002) (acknowledging the strong incentive created by this exclusivity). In a comprehensive review of all ANDAs filed between 1992 and 2001, an FTC study found that, of the 53 patent infringement cases that had been resolved in that timeframe, 20 settled and 30 were litigated to resolution.[5] FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, at 16 (July 2002). Among the 20 settlements, 9 included either a supply agreement or a license and 9 included exclusion payments. *Id.* Of the litigated cases, 73% were resolved in favor of the generic challenger. *Id.*

In connection with a consent decree obtained in one of the early exclusion payment cases, the FTC announced that "[p]harmaceutical firms should now be on notice . . . that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues with a potential for serious consumer harm." *Abbott Labs. and Geneva Pharms.*, No. C-3945, (FTC Mar. 16, 2000) (Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary), *available at* http://www.ftc.gov/os/2000/03/hoeschtandrxcommstmt.htm. After that announcement, pharmaceutical manufacturers stopped entering into exclusion payment settlement agreements. *See* FEDERAL TRADE COMMISSION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICAID PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, at 4 (Jan. 2005). Since that time, generic manufacturers have instead either negotiated settlements that include early entries via licenses or continued to litigate their cases. *Id.*

5. In the remaining 3 instances, the cases were resolved either because the patents expired before the expiration of the 30-month stay or the NDA was withdrawn for safety reasons.

The FTC's enforcement efforts in these exclusion-payment cases are vital to this industry. The enormous consumer gains resulting from generic entry – whether by winning the patent litigation or obtaining licensed entry through settlement – are shown by a few examples. Barr Laboratories challenged the patents protecting Eli Lilly's drug Prozac. In the midst of that patent challenge, Barr stated that it would settle only if the agreement included an exclusion payment of at least $200 million. *See* Bethany Mclean, *A Bitter Pill*, FORTUNE, Aug. 2001, at 5. Lilly refused the demand because "such a settlement violated antitrust laws, and it isn't morally right." *Id.* (quoting Lilly CEO). So Barr continued litigating the case and ultimately obtained a judgment invalidating the Prozac patents. The resulting early entry of generic Prozac saved consumers an estimated $2.5 billion. *See* Comment of the Generic Pharmaceutical Ass'n in Support of Citizen Pet., FDA Docket No. 2004P-0075/CP1, at p. 3 (filed May 21, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf.

Similar consumer savings result when generics enter before the conclusion of patent litigation. For instance, in 1998, several generic manufacturers filed ANDAs seeking to market generic versions of AstraZeneca's Prilosec. Although the patent on the chemical entity expired in October 2001, AstraZeneca claimed that the proposed generic products infringed various formulation patents, the last of which is slated to expire in 2007. *See Astra Aktiebolag v. Andrx Pharm.*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002). In October 2002, the district court ruled that generic manufacturer KUDCo's product did not infringe AstraZeneca's patents. *Id.* at 433. Two months later – and over four years before the relevant patents were to expire – KUDCo launched generic Prilosec at a 20% discount to the brand. Susan Jaffe, *Medicaid Hopes to Save Millions With Generic Pill*, CLEVELAND PLAIN DEALER, Dec. 14, 2002, at B2. Generic Prilosec quickly captured 60% of the $3 billion market, resulting in consumer savings of at least $360 million per year. *See* AstraZeneca PLC, First Quarter Results 2003 at p. 2, *available at* http://www.astrazeneca.com/sites/7/imagebank/

migratedpress/q12003narrative.pdf. The Federal Circuit ultimately affirmed the district court's ruling in December 2003. *See In re Omeprazole Patent Litig.*, 84 Fed. Appx. 76 (Fed. Cir. 2003).

By way of another example, GlaxoSmithKline ("GSK") was in the midst of litigating its Paxil patents against generic challenger Apotex when the Hatch-Waxman 30-month stay (21 U.S.C. § 355 (j)(5)(B)(iii)) expired. GSK then sought an injunction to preclude Apotex from the market until the litigation concluded, but the court denied that request. *See SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003). Apotex launched its generic Paxil product in September 2003 – over three years before the Paxil patents were slated to expire. *See* Press Release, Apotex Corp., Apotex Launches First Generic Version of Paxil: Affordable Product Kept from Consumers for Years Too Long! (Sept. 8, 2003), *available at* http://www.apotex.com/PressReleases/20030908-01.asp. In April 2005, the Federal Circuit affirmed judgment in favor of Apotex, ruling that GSK's patent is invalid. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005). We estimate that the savings to consumers from September 2003 until April 2005 (when the patent litigation concluded) were more than $1 billion; the savings from September 2003 until December 2006 (when the patents would have expired) will exceed $ 2 billion.[6]

None of these consumer savings would likely have occurred if the Court of Appeals panel's ruling had been the law at the time. If exclusion payments are permissible under the antitrust law – if the CEOs of Lilly and the other manufacturers are told that they are *wrong* to believe that an exclusion payment settlement "violate[s] antitrust laws, and it isn't morally right" – such settlements will very likely become the norm. The vast majority of pharmaceutical patent cases can be settled. Keith Leffler et al., *Efficiency Trade-Offs in Patent Litig. Settlements: Analysis Gone Astray?*, 39 U.S.F.L. Rev.

6. We assume an averaged generic penetration rate of 75%, a generic discount of 45% off the brand price, and a market of $2 billion per year (at the brand price).

33, 42 (Fall 2004).[7] The wide disparity between the profits gained by a generic challenger and the profits lost by the brand manufacturer when a generic enters allows for a wide range of settlement possibilities. *Id.* Even if a generic challenger believes that there is a 100% chance that the patent will be found to be invalid, the case can nevertheless be settled with an exclusion payment if the patentee believes that there is anywhere from a 6% to a 100% chance of invalidity. *Id.* Moreover, of the cases that can be settled, both the brand and generic manufacturer have a strong economic incentive to divide the monopoly profits between themselves by means of an exclusion payment rather than to share those profits with consumers by means of licensed generic entry. *Id.* at 44. So, except in the rare instance in which each party believes that he is virtually certain to win, pharmaceutical patent cases can always be settled, and both parties' economic incentive is to settle with an exclusion payment rather than licensed entry.

**The FTC Decision And Its Rationale**

The unanimous FTC decision applied well established law and economic principles to determine the competitive effects of a patentee's paying cash to its rivals in exchange for withdrawing a patent challenge and staying out of the market. The key marketplace fact is that, as of the date of the agreements at issue,[8] it was *uncertain* whether Upsher and/or ESI would succeed in their efforts to compete with Schering. Upsher and ESI might have lost the patent litigations, but they also might have won.

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7. Of course, not all pharmaceutical patent cases that can be settled are in fact settled. Factors extraneous to the merits of a particular case sometimes make settlement unattractive to one or more of the parties. For example, the patentee lacks incentive to settle if he has another entry-defeating tactic in reserve in the event of a loss in the patent litigation. See Complaint, *CVS Pharmacy, Inc. et al. v. Abbott Laboratories et al.*, No. 05-340-KAJ (D. Del. Aug. 17, 2005) (alleging that by the time patentee had lost patent litigation, patentee had switched branded product from capsules to tablets, thus preventing FDA from approving A-B-rated generic).

8. The legality of an agreement under the antitrust laws is determined as of the date that the agreement was entered into. *See, e.g.*, XI Herbert Hovenkamp, ANTITRUST LAW ¶ 1901, at pp. 185-86 (1998); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir. 1981).

The uncertainty as to Schering's ability to prevent Upsher's and ESI's entry was substantial. The principal issue in both litigations was whether the generic products infringed Schering's patent. Infringement determinations are inherently fact intensive and subject to great uncertainty. Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1934 n.179 (2002) ("the effort to map the words of patent claims to products is inherently an uncertain one"); *see also* Richard J. Gilbert & Willard R. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 47 n.8 (2001) ("the boundaries of intellectual property defy accurate survey to a much greater extent than do those of tangible property"). Both litigations also involved assertions of patent invalidity or unenforceability, an issue that is "as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts." *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir. 1950) (Hand, J.).

The uncertainty stems in large part from the fact that patents do not receive anywhere near the scrutiny in the Patent and Trademark Office that they receive in subsequent court challenges. PTO proceedings are conducted *ex parte*, and the PTO is simply overwhelmed: "With yearly application totals approximating 300,000, they arrive at a rate of about 1,000 each working day." FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, at Ch. 5 p. 4 (Oct. 2003). Examiners must act quickly on these applications: "new examiners have 25 hours, and more experienced examiners have 20 hours, to examine a biotechnology patent." *Id.* at Ch. 1 p. 34.

The circumstances are radically different when the validity or enforceability of a patent is challenged in court, where the proceedings are *inter se*, the court hears from opposing experts, and the issues generally receive as much time and attention as is necessary. The result is that, despite the statutory presumption of validity, 35 U.S.C. § 282, half of all litigated patents are ultimately found to be invalid or unenforceable.

John R. Allison & Mark A: Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 206 (1998).[9]

In determining the antitrust significance of the key marketplace fact of uncertainty, the FTC was not writing on a blank slate. It is unlawful for a firm to pay a current or potential competitor to exit or stay out of the market. *See, e.g., United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899); *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 48-49 (1990).[10] It is equally unlawful to pay to eliminate *uncertain* competition:

> [T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition.

XII Herbert Hovenkamp, ANTITRUST LAW ¶ 2030b at 175 (1999). For example, assume that A and B are competitors and A tells B that there is a 30% chance that A is going to lower her price

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9. As a matter of public policy, there is not necessarily any reason to be alarmed at the disparity between a harried patent examiner's and a court's view of the validity of a patent. With the notable exceptions of pharmaceutical and chemical patents, the vast majority of issued patents have little economic significance. So it is efficient and appropriate to have a patent process consisting of initial issuance based on a less-than-searching review, followed by a careful judicial review of the comparatively few patents that have genuine economic significance. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U.L. Rev. 1495 (2001). What is not good policy -- what makes no sense at all -- is to adopt an antitrust rule that would permit patentees who have gotten only half-way through this process to declare victory and then pay their would-be competitors to respect that "victory."

10. Often the conspirators agree that each of them will be allocated a particular territory, and the consideration for the agreement is the mutual promise not to compete in the other's territory. But the antitrust analysis does not change merely because, as here, only one competitor is allocated a territory and the consideration is cash rather than a promise. *See Addyston Pipe & Steel*, 175 U.S. at 241; *see also Garot Anderson Agencies, Inc. v. Blue Cross & Blue Shield United*, 1993 U.S. Dist. LEXIS 3446, at *38-39, 1993-1 Trade Cas. ¶ 70,235 (N.D. Ill. Feb. 26, 1993) (rejecting argument that agreement was not market allocation because only one defendant received a market).

next week. It is clearly unlawful for B to pay A to refrain from lowering her price. If C tells D that there is a 30% chance that C will enter into D's geographic market, it is clearly unlawful for D to pay C not to enter. *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001 (en banc) (exclusionary conduct is unlawful when it "is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes"); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir. 1979) (unlawful to agree to suppress a product of which only a prototype had been made); *Microbix Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680, 698 (D. Md. 2000) (finding evidence sufficient to support a finding that exclusive contract was unlawful even though causation theory required showing "that Plaintiff would have successfully secured a manufacturing facility, obtained FDA approval, developed the [product] in commercial quantities, and marketed the product during the relevant timeframe"). Of course, in order to recover damages under Section 4 of the Clayton Act, private plaintiffs are required to show that, absent the unlawful conduct, the competition would in fact have occurred. But no such additional showing was required in this FTC proceeding. *See, e.g., Spiegel, Inc. v. Federal Trade Comm'n*, 494 F.2d 59, 62 (7th Cir. 1974).

The FTC had the task of applying these principles in a circumstance in which the patentee had *both* granted an early-entry license to the challenger *and* made a substantial payment to the challenger. The issue was whether the early-entry licenses resulted in less competition than would likely have occurred absent the payments, viewed from the vantage point of the time when there was uncertainty as to who would prevail in the patent litigations. The FTC knew how much competition was provided by the early-entry licenses, so the real task was to determine how much competition would likely have occurred in the absence of the payments – to determine the baseline for a competitively benign settlement agreement.

Invoking the well-established economic concept of "expected" *i.e.*, probability-adjusted, outcomes of litigation,[11] the FTC held that the proper baseline is the amount of competition that *the parties themselves* believed, *as of the time of the agreements*, was *probable*. Pet. App. 76a-77a; *see also* Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1758 (2003) (proper baseline is the "competition that the patentee could . . . expect *ex ante* to exclude after trial"); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. OF ECON. 391, 395 (Summer 2003) ("A patent settlement cannot [lawfully] lead to lower expected consumer surplus than would have arisen from ongoing litigation").

The parties' own views of the probability-adjusted outcome of litigation is an eminently sensible competitive benchmark. It takes account of the key marketplace fact that patent litigation is inherently uncertain; it focuses on the facts as of the date of the agreement; and it acknowledges that the parties themselves are best situated to assess the likely outcome of the litigation. Moreover, the alternative — an *ex post* determination of patent validity or infringement by a court as part of a subsequent antitrust claim — is both unfairly biased against a finding of antitrust liability (Pet. App. 85a-87a) and self-defeating.[12]

The competitive baseline used by the FTC is also consistent with that used by courts in determining the legality of intellectual property settlements. In *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931), the Court held that, absent evidence of unduly restrictive ancillary agreements or of unlawful accumulation of market power, the parties could

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11. *See* William M. Landes, *An Economic Analysis of Courts*, 14 J. L.& ECON. 61 (1971); *see also* George L. Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1 (1984); and Robert T. Cootner and Daniel L. Rubinfeld, *Economic Analysis of Legal Disputes*, 27 J. OF ECON. LIT. 1067 (1989).

12. Permitting any settlement of a patent challenge is efficient only to the extent that society saves the costs of the patent litigation. Society does not save those costs if they are merely deferred until the subsequent antitrust case.

lawfully settle a patent litigation over blocking patents by entering into a cross-license agreement. A settlement by way of such cross-licenses is lawful precisely because it presumably reflects "a division of royalties according to *the value attributed by the parties* to their respective patent claims. . . ." *Id.* at 171 (emphasis added); *see also United States v. Singer Mfg. Co.*, 374 U.S. 174, 199 (1963) (White, J., concurring) (settlement of patent interference was unlawful because it did not involve "purely unilateral action" but instead involved "collusion among applicants to prevent prior art from coming to or being drawn to the [PTO's] attention"); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (exclusionary power of pending patent application "depends on how likely the parties consider it to be that a valid patent will issue"); *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50, 60-61 (2d Cir. 1997) (absent payment by rights holder to alleged infringer, settlement of intellectual property litigation is presumed to flow from "hard-nosed trademark negotiations" and "the result should accord with how the parties view their respective rights").

With the competitive baseline in place, the FTC turned to whether the cash payments likely reduced the amount of competition below the baseline. The FTC began by examining two economic facts. First, earlier entry gains far less profits for the generic than it loses for the brand, and consumers get the difference. Pet. App. 77a. Both parties' economic incentive, therefore, is for the brand to simply pay the generic and split the amount that earlier entry would have brought to consumers. *Id.* at 77a-78a.

Second, the FTC again relied on the economic concept of "expected" litigation outcomes: the patentee would not make a payment to the challenger unless the payment reduced competition to a level below that expected by the patentee. Likewise, when the challenger requires a payment in order to agree to the entry date offered by the patentee, that entry date must provide less competition than the challenger himself expects under litigation. Shapiro, *Antitrust Limits to Patent Settlements*, at 407-08 ("The patent holder would not pay more than avoided litigation costs unless it believed that it was

buying later entry than it expects to face through the litigation alternative"); Hovenkamp, *Anticompetitive Settlement of Intellectual Property Disputes*, at 1759 ("The reason the patentee is willing to make this payment is precisely because the settlement will permit it to exclude competition from the market"). The FTC summarized the relevance of these two economic facts:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

Pet. App. 76a-77a (citations omitted).

With respect to the Schering/Upsher agreement, the FTC concluded, in a finding of fact entitled to judicial deference, that there was no other purpose for the cash payments. *Id.* at 140a-141a. And the economic evidence that the payments were in exchange for reduced competition was further supported by the history of the parties' negotiations and by the terms of the agreement itself. *Id.* at 93a-107a. With respect to the Schering/ESI agreement, the defendant offered no other explanation for the payment, and, again, the economic evidence was supported by the express terms of the agreement. *Id.* at 142a-145a.

The FTC's decision concerning the proper competitive baseline was supported by caselaw and the application of standard economic principles to the real marketplace facts. Its conclusion that Schering's payments likely reduced competition below that baseline was supported by economics, the negotiation histories, the terms of the agreements, and the absence of alternative explanations.

## ARGUMENT

### I. THE COURT SHOULD GRANT REVIEW IN ORDER TO CORRECT THE COURT OF APPEALS' FUNDAMENTAL ERRORS OF LAW.

The Court should grant review in this case because the FTC's analysis was fundamentally sound and the Court of Appeals panel committed substantial legal error in reversing it. These considerations support the grant of review on the unique facts of this case because, through the workings of 15 U.S.C. § 45(c), the panel's erroneous decision would disable the FTC from enforcing the antitrust law against agreements that threaten enormous harm to consumers.

That the Court of Appeals panel committed fundamental error is shown, first, by the fact that the panel seems literally not to have understood the legal and economic foundation of the FTC's decision:

- The panel stated that the FTC's analysis did not include "inquiry into the merit of the '743 patent litigation." Pet. App. 9a. In fact, the very core of the competitive baseline adopted by the FTC is the merits of the '743 patent litigation as viewed by the parties themselves at the time of the agreements.

- The panel noted that both Upsher and ESI demanded substantial cash payments in addition to the agreed entry dates. *Id.* at 4a, 7a. The panel seems not to appreciate that those facts — together with the fact that in both instances Schering was willing to make the demanded payments — were clear economic evidence that the parties were reducing competition to a level below the amount that they themselves otherwise expected.

- The panel derided as "arbitrary" the FTC's conclusion that payments up to the amount of saved litigation costs would not be unlawful. *Id.* at 10a. It is clear, however, that payments in the amount of saved litigation costs do not reduce expected competition. Hovenkamp, *Anticompetitive Settlement of Intellectual Property Disputes*, at 1758 ("Even a patentee sure to win would be willing to pay a defendant a sum up to the cost of the lawsuit to end the litigation and avoid that cost").

• The panel faulted the FTC for failing to provide record evidence that, absent the payments, the parties would in fact have agreed on earlier entry. Pet. App. 30a-31a. But the economic and other evidence showed that the payments reduced the actual amount of competition under the early entry licenses below the amount that the parties themselves expected under litigation. Whether additional competition would in fact have occurred, but for the payments, is an important question of causation in private litigation challenging these agreements, but is irrelevant in an FTC administrative proceeding.[13]

Rather than contending with the FTC's legal and economic analysis, the panel simply denied, without discussion or analysis, the essential marketplace fact that drove that analysis. Invoking the statutory presumption of validity, the panel denied the fact that, at the time of the agreements, there was uncertainty as to who would win the patent litigations. *Id.* at 18a. The panel held that, "[b]y virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent." *Id.* Based on this supposed ironclad "legal right to exclude"[14] the panel thus adopted as its competitive baseline the amount of competition assuming that Schering's patent was valid and infringed, *i.e.*, zero competition. The rest of the panel's analysis flowed from this fundamental error.

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13. In private cases, plaintiffs attempt to show causation by demonstrating that, but for the payments, the parties *either*: (1) would not have settled and the challenger would have won the patent litigation; or (2) would have settled with a license granting earlier entry (or a lower royalty rate).

14. The panel disregarded this Court's frequent admonition that "the word 'right' is one of the most deceptive of pitfalls; it is so easy to slip from a qualified meaning in the premise to an unqualified one in the conclusion. Most rights are qualified." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985), quoting *Lorain Journal Co. v. United States*, 342 U.S. 143, 155 (1951), which quotes *American Bank & Trust Co. v. Federal Reserve Bank*, 256 U.S. 350, 358 (1921).

The panel's decision was deeply flawed even assuming that its antitrust analysis should, or could rationally, be based on legal presumptions regarding infringement or validity. The panel was wrong as to who has the burden of proving both infringement and validity. As to infringement – the central issue in both of the patent litigations – it is hornbook law that the patentee, not the challenger, bears the burden of proof at all stages of the litigation. *See Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004). And the patentee also bears the burden of proof as to validity where, as here, the patentee seeks to exclude the challenger from the market without a full adjudication on the merits. *See, e.g., Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) ("at the preliminary injunction stage . . . the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity" (emphasis in original)); *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994) (same). If the burden of proving validity is on a patentee who seeks a court's assistance in obtaining pre-trial exclusion of a competitor, so too should that burden be borne by a patentee who eschews a court's assistance and oversight and instead pays a competitor not to enter.

The panel's more fundamental error was in premising its antitrust analysis on a legal presumption rather than on an economic analysis of marketplace realities. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) (antitrust analysis must be based on "market facts"). The rebuttable presumption of validity that undergirds the panel's entire analysis is one small piece of a larger patent *system* in which patents are issued *ex parte* and are subject to plenary review in the courts – courts that find more than half of all litigated patents to be invalid. A party that has been issued a patent by the PTO but has not yet succeeded in court is not nearly even halfway home. In the pharmaceutical arena, Congress has not only made court review plenary, but has offered a bounty for successful generic challengers. The generics' success rate – despite the presumption relied on by the panel – is greater than 70%. The FTC's economic analysis is based on the marketplace reality as viewed by the parties

themselves, and it therefore captures the economic significance of the entire patent system, not merely one tiny aspect of it.

Moreover, there is abundant evidence that Congress never intended the rebuttable presumption to create the ironclad exclusion that the panel inferred. In the Hatch-Waxman Act, Congress granted to patentees the ability to automatically exclude generic challengers, but only for a limited period of time – 30 months. After the expiration of 30 months, the FDA is free to approve a generic drug for marketing regardless of whether patent litigation is ongoing. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Similarly, in pharmaceutical as well as other patent cases, courts applying patent law frequently deny preliminary injunctions on the ground that, until a judicial finding of validity and infringement, the alleged infringer has a "right to compete." *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990).

Congress' understanding that patents are not ironclad, and that exclusion payment agreements are anticompetitive, was made perfectly clear in the hearings leading up to the recently enacted settlement-reporting legislation.[15] *See, e.g.*, 148 CONG. REC. S7566 (daily ed. July 20, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type of reverse payment collusive arrangements appalling"); 146 CONG. REC. E1538-02 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman) ("requir[ing] companies seeking to reach secret, anticompetitive agreements to disclose them to the FTC . . . [will] ensure that existing antitrust and drug approval laws are enforced to the letter"); 147 CONG. REC. S3711 (daily ed. Apr. 6, 2001) (remarks of Sen. Leahy) (legislation is intended to give to the FTC "the information they need to prevent manufacturers of patented drugs – often brand-name drugs – from simply paying generic drug companies to keep lower-cost products off the market").

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15. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

Congress went out of its way to commend the FTC for its work in uncovering and prosecuting exclusion payment cases, including this one. *See, e.g.*, 148 CONG. REC. S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws"); 148 CONG. REC. S7460 (daily ed. July 29, 2002 ) (remarks of Sen. Hatch) ("We ought to pay attention to the experts at the FTC and elsewhere who have spent so much time on this issue"); 146 CONG. REC. S7908-01 (daily ed. July 27, 2000) (remarks of Sen. Leahy) (congratulating the FTC for "instantly lower[ing] the boom on the companies").

Far from being consistent with Congress' intent, the panel's decision appears to be animated by an express antipathy to Congress' decision to encourage challenges to pharmaceutical patents. *See* Pet. App. 31a. Noting the Hatch-Waxman Act's patent-challenge incentives, the panel states with apparent alarm that, "This statutory scheme could then cost Schering its patent." *Id.* That alarm prompted the panel to conclude that Schering should be permitted to make exclusion payments in order to "realize[] the full potential of its infringement suit – a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future." *Id.* Permitting payments to terminate patent challenges is not a proper judicial response to Congress' decision to encourage those challenges.

The panel's related concern regarding the "caustic environment of patent litigation" and its costs (*id.* at 33a) also misses the mark. The panel failed to appreciate "the importance to the public at large of resolving questions of patent validity" so that society does not "grant monopoly privileges to the holders of invalid patents." *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993). And while patent litigation is costly, the FTC permitted payments up to the amount of saved litigation costs; therefore, by definition, exclusion payments found unlawful under the FTC's analysis would result in lost consumer welfare greatly disproportionate to the relatively modest costs of patent litigation. Herbert

Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. 712, 717 (2004).

The panel also asserts that the FTC's analysis would render all patent settlements unlawful because they all involve either explicit or "implicit" consideration flowing from the patentee to the challenger. Pet. App. 32a. This is plain error. Absent an exclusion payment, a settlement by means of licensed entry (*without* any exclusion payment) is clearly not unlawful under the FTC's analysis. The baseline for a competitively benign settlement is the amount of competition expected by the parties themselves, and absent an exclusion payment, the terms of a license agreement – the entry date and the royalty rate – will reflect the parties' respective views of the strength of the patent claim. The panel's example of "implicit consideration" – the patentee's waiver of a damage claim against a challenger that has entered the market before the conclusion of patent litigation (*id.*) – is simply a species of license (*i.e.*, a retrospective, rather than a prospective, license.)

Finally, the panel's assertion that prohibiting exclusion payments would "reduce the incentive to challenge patents" (*id.* at. 33a) is illogical. Consumers are helped not by patent challenges, but by *successful* patent challenges, *i.e.*, challenges that result in generic entry through either prevailing in the patent litigation or obtaining a license. Payments in exchange for exclusion result in more exclusion, not more entry.

## II. THE COURT SHOULD GRANT REVIEW IN ORDER TO RESOLVE A CONFLICT BETWEEN THE CIRCUITS.

The Court of Appeals panel and the FTC differed sharply over the proper competitive baseline. Relying on the rebuttable presumption of validity, the panel's baseline is the amount of competition assuming that the patent is valid and infringed. Relying on marketplace reality, the FTC's baseline is the amount of competition expected by the parties themselves. The Court of Appeals for the Sixth Circuit has also ruled on this issue and has adopted the same competitive baseline used

by the FTC. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 125 S. Ct. 307 (2004).

In *Cardizem* the patentee paid the challenger to stay out of the market pending resolution of the patent litigation (the automatic 30-month stay had expired). Relying on marketplace realities rather than a presumption of validity, the Court held that a brand manufacturer's patent does not create an "'impenetrable' legal impediment [to the generic challenger's] production and sale of its FDA-approved generic product." *Id.* at 914. Defendants' plea to adopt a baseline based on the rebuttable presumption of validity crashed headlong into economic reality: if the "independent durability of [the brand manufacturer's] patent and the validity of its infringement claim" had been sufficient on their own to exclude a generic competitor from the market, then the brand manufacturer "would not have paid [the generic competitor] $89 million to effect what the patent and infringement suit had already accomplished." *Id.* at 915. The patentee's allegations of infringement merely created in the generic challenger a "fear of damages in the patent infringement litigation," *id.* at 911, a fear that *may* or *may not* have prompted the challenger, acting "unilaterally, and legally [to refrain from] bring[ing] its generic product to a manifestly profitable market." *Id.* at 915. The patentee's payments gave it something that the patent law did not — "the Agreement *guaranteed* to [the brand manufacturer] that its only potential competitor at that time . . . would, for the price of $10 million per quarter, refrain from marketing its generic version of Cardizem CD even after it had obtained FDA approval." *Id.* at 907 (emphasis added); *see also Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (agreement caused antitrust injury because "HMRI's [exclusion payments] were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic").

Under the Eleventh Circuit's ruling here, the antitrust laws are apparently powerless to police such exclusion agreements. Pet. App. 16a ("neither the rule of reason nor the *per se* analysis is appropriate in this context"). The Sixth Circuit reached

exactly the opposite conclusion, holding that exclusion payment settlements are *per se* unlawful. *In re Cardizem*, 332 F.3d at 900. In that Court's words, "[I]t is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908.

The split between the Sixth and Eleventh Circuits is fundamental and stark. The Sixth Circuit's analysis is closely akin to that of the FTC, but that Circuit Court would make the further decision that such payments are so unlikely to ever have any procompetitive benefits that they should be condemned as *per se* unlawful. Review by this Court is necessary to ensure that the Eleventh Circuit's ruling – starkly at odds with that of another Circuit – does not dictate FTC enforcement policy on this important issue.

## CONCLUSION

For the foregoing reasons, NACDS respectfully submits that this Court should grant certiorari to correct the Court of Appeal's fundamental errors and to resolve an intolerable conflict between two Circuits.

Respectfully submitted,

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No. 05-273

In The
# Supreme Court of the United States

FEDERAL TRADE COMMISSION,

*Petitioner,*

v.

SCHERING-PLOUGH CORPORATION, *ET AL.*,

*Respondents.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit**

## MOTION OF THE PUBLIC PATENT FOUNDATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF OF *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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## MOTION OF THE PUBLIC PATENT FOUNDATION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the Public Patent Foundation, Inc. ("PUBPAT") respectfully moves this Court to grant it leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of certiorari. Counsel for Petitioner has consented to the filing of this brief, counsel for one of the Respondents, Upsher-Smith Laboratories, Inc., has withheld consent, and counsel for the other Respondent, Schering-Plough Corporation, did not respond to a request for consent.

PUBPAT is a not-for-profit legal services organization founded in 2003 to represent the public's otherwise unrepresented interests in the patent system, and most particularly the public's interests against the harms caused by wrongly issued patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education and it is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute and by private donations from the public.

PUBPAT has argued for sound patent policy before the United States Court of Appeals for the Federal Circuit, the United States Patent & Trademark Office, the European Parliament, and the United States House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property. PUBPAT has also requested that the Patent Office reexamine specifically identified wrongly

issued patents causing significant harm to the public. The Patent Office has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

PUBPAT has an interest in this matter because the decision of the Eleventh Circuit below will have a significant negative effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against the harm caused by unsound policy with respect to patents. More specifically, PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

Although technically an antitrust case, this matter involves an evaluation of the exclusionary power of patents. As such, PUBPAT believes its brief, authored by a registered patent attorney and addressing that issue, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true since PUBPAT has significant experience in determining the exclusionary power of patents, as such an exercise is a fundamental part of each of its core activities.

Accordingly, PUBPAT respectfully requests that the Court grant leave to file the attached brief as *amicus curiae*.

Respectfully submitted,

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## INTEREST OF THE *AMICUS CURIAE*

PUBPAT is a not-for-profit legal services organization founded in 2003 to represent the public's otherwise unrepresented interests in the patent system, and most particularly the public's interests against the harms caused by wrongly issued patents and unsound patent policy.[1] PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education and it is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute and by private donations from the public.

PUBPAT has argued for sound patent policy before the United States Court of Appeals for the Federal Circuit, the United States Patent & Trademark Office, the European Parliament, and the United States House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property. PUBPAT has also requested that the Patent Office reexamine specifically identified wrongly issued patents causing significant harm to the public. The Patent Office has granted each such request. These accomplishments have established PUBPAT as a leading provider of public service patent legal services and one of the loudest voices advocating for comprehensive patent reform.

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and that no person or entity, other than *amicus curiae* and its counsel made a monetary contribution to the preparation or submission of this brief.

PUBPAT has an interest in this matter because the decision of the Eleventh Circuit below will have a significant negative effect on the public's interests represented by PUBPAT and because PUBPAT's mission is to represent those interests against the harm caused by unsound policy with respect to patents. More specifically, PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

Although technically an antitrust case, this matter involves an evaluation of the exclusionary power of patents. As such, PUBPAT believes its brief, authored by a registered patent attorney and addressing that issue, provides the Court with relevant legal and factual information that may not otherwise be brought to its attention. This is especially true since PUBPAT has significant experience in determining the exclusionary power of patents, as such an exercise is a fundamental part of each of its core activities.

## SUMMARY OF ARGUMENT

The Court of Appeals in this case made the erroneous assumption that the exclusionary power of a patent is always measured by its full statutory term. Not only is that assumption unsupported by empirical analysis of patents generally, which shows that only about one half of all asserted patents have any exclusionary power whatsoever, such assumption is categorically contradicted when a patentee and accused infringer agree on a date prior to the patent's expiration at which time the alleged infringer can,

without compensation or consequence, freely sell its product. In those circumstances, the exclusionary power of the patent, with respect to *that* product, is measured by the agreed to pre-expiration free-entry date, because such date is, in effect, a specifically tailored patent expiration date vis-à-vis that product.

If an accused infringer is given consideration in addition to a pre-expiration free-entry date, then the exclusionary power of the patent with respect to the accused infringer's product is equivalent to some date prior to the agreed-to pre-expiration free-entry date, because the extra consideration, in the absence of any other explanation, is in exchange for additional delay in entry. The Court of Appeals ignored this simple truth in this case and, in effect, promulgated a virtual exemption from antitrust law for any agreement that involves a patent. Such an exemption conflicts with this Court's precedents and with sound legal and economic theory.

Further, the Court of Appeals' unwillingness to apply sound antitrust principles for fear that such may deter pro-competitive patent settlements is based on unsound circular reasoning. By definition, application of sound antitrust principles can only deter conduct that has an anti-competitive effect. More specifically with respect to this case, deterring anti-competitive patent settlements, above and beyond protecting competition, also has the significant pro-competitive effect of encouraging more patent challenges to result in judgments.

Therefore, to protect the public from anti-competitive settlements of patent infringement litigation whereby a potential competitor is offered a share of the monopoly profits that can be maintained if it stays off the market,

this Court should grant the petition for a writ of *certiorari* and correct the mistake made by the Eleventh Circuit in this case.

## REASONS FOR GRANTING THE PETITION

People unfamiliar with the patent system, including specifically the Court of Appeals in this case, tend to give patents entirely too much credit. Rather than being rock-solid undeniable fortresses of legal dominance over a segment of technology, patents today give their owner nothing more than, at best, a fifty-fifty chance of having any exclusionary power at all. As such, the Court of Appeals' assumption that any patent has an exclusionary power equal to its full term over any product is without merit. *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005), *petition for cert. filed* (Aug. 29, 2005) (No. 05-273).

If a patent holder agrees to allow the sale of a certain product prior to a patent's expiration, it is possible to determine the exclusionary power of the patent with respect to that product without resort to full-blown patent litigation. One need only look at the details of the agreement and identify what the parties negotiated the exclusionary power of the patent to be. Instead of recognizing this fundamental truth of the patent system, the Court of Appeals instead chose to blindly adopt the position that all patents are to be presumed to have total exclusionary power over any product against which they are asserted for their entire term and, thus, any settlement of a patent infringement allegation that allows an accused product to enter the market prior to the patent's expiration is exempt

from the competition laws. This conclusion is wrong and, if left undisturbed, will lead to substantial harm being caused to the American public through lessened competition and its attendant higher prices and lower choices. To be sure, this effect will be felt not only in the pharmaceutical industry, but in many other industries as well. As such, the petition for a writ of *certiorari* should be granted.

## I. THE COURT OF APPEALS ERRED BY FAILING TO RECOGNIZE THAT SCHERING'S PATENT DID NOT HAVE THE POWER TO EXCLUDE ALL GENERIC PRODUCTS FOR ITS ENTIRE TERM.

There is no one measure of the exclusionary power of a patent. Such is merely a relative term describing the capability of a patent to prevent the manufacture, use or sale of a specific product. The same patent can have many different exclusionary powers depending upon the characteristics of the product against which it is asserted. The exclusionary power of a patent is also affected by several other factors, including the capabilities of the party against whom it is asserted to mount an invalidity or non-infringement defense. In no case, however, can a patent be said to have the "potential" to exclude everything. At most, any given patent can only have the "potential" to exclude some defined thing or class of things.

The Court of Appeals made a critical error in this case by assuming that Schering-Plough's ("Schering") patent had an exclusionary power equivalent to its full term with respect to any generic product. This not only failed to recognize that the patent had the potential to have *no* exclusionary power with respect to those products, it was

also contrary to the significant empirical evidence regarding the exclusionary power of patents generally that is available from the literature.

While it is correct that *one* way to determine the exclusionary power of a patent with respect to a certain product is through resolution of the patent dispute by court judgment, that is not the *only* way to do so. Another effective way to determine the exclusionary power of a patent is through resolution of the dispute by agreement between the parties. It is the resolution of the dispute, not the means through which the dispute is resolved, that provides a measurement of the exclusionary power of the patent with respect to the specific product against which it has been asserted.

### A. The Exclusionary Power of Patents, Generally, Is Much Less Than Their Full Term.

Patents are not as powerful as many presume. First, roughly half of all issued patents later challenged in litigation are proven to be invalid. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 (1998) (demonstrating that 46% of patents litigated to judgment on validity issues are held invalid); Patstats, U.S. Patent Litigation Statistics, University of Houston Law Center, available at http://www.patstats.org/2003.html (detailing that, in 2003, of 201 validity decisions, the patent was found to be invalid 117 times, 58%).

Second, even if no challenge to the validity of a patent is made, accused infringers still frequently nullify any exclusionary power of the asserted patent with respect to their product by proving that their product does not